

EXHIBIT C

From: John Schuetter [jschuetter@apacgroupe.com]
Sent: Friday, March 23, 2012 3:41 PM
To: mguzman@apacgroupe.com; aboswinkle@apacgroupe.com; krodriquez@apacgroupe.com
Subject: Fw: Additional Info
Attachments: PCAB article harvardPDF.pdf; PCAB Flyer.pdf; AMAresolutiononcompounds.pdf

This is a good rep. We need to meet her. We can save \$

-----Original Message-----

From: Jessica Markley <jessica@duntonmedical.com>
Date: Fri, 23 Mar 2012 14:35:55
To: John Schuetter<jschuetter@apacgroupe.com>
Subject: Additional Info

John,

I am attaching a few documents for you to review. One is an article regarding the safety and importance of using PCAB accredited compounding pharmacies for a cheaper alternative to the branded and why they aren't all created equal, and the other is an info sheet on the PCAB accreditation of US Compounding. Lastly, there is a statement from the American Medical Association that supports the use of compounding whereas a facility with the PCAB (Pharmaceutical Compounding Accrediting Board) certification is used. You are supported from the FDA, DEA, AMA, and VA/Medicare not to mention third party insurers when you use a PCAB compounder. If you aren't, you are completely open to many liabilities discussed below.

Please call with any questions, I can help you work through a lot of issues just based on experience with a lot of other offices and what they have done to ensure their safety and eliminate liability and save a lot of money.

Jessica Markley
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Filename: PCAB article harvardPDF.pdf

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Why It's Important to Know Your Compounder: Why Accreditation is Necessary When Looking for Alternatives to Branded Medication

By: Michael Fancetti, Harvard Medical School Faculty (August 8, 2011)

Many physician offices around the United States are looking for a way to cut their overhead and the costs that are associated with running a medical business. Increasingly so, many physicians reimbursements from third party insurers and Medicare are decreasing and putting a tight budget into the hands of many offices who have never found the financial constraints before this recent recession. Whatever the case may be, it is important to do some homework on what you are buying and from whom.

Many medical facilities are looking for ways to get around the traditional medical model of buying pharmaceuticals from a wholesaler and trying on their own to buy direct from a foreign facility or a compounding pharmacy. There are a few problems with buying a foreign drug, particularly from Mexico and Canada. There are numerous documented cases of drugs that are filtered through Canada that have actually come right from a dirty facility and completely unregulated market in Mexico. Secondly, although Canada has decent regulation when it comes to the distribution of pharmaceuticals, there are plenty of reasons why you should consider a compounding pharmacy with the PCAB or Pharmacy Compounding Accreditation Board seal of approval on them. If an office is purchasing from someone other than this certified compounding clinic, you have plenty to be worried about, right down to your medical licensure and liability. Recent cases in California and Nevada of patients who died from dirty vials and unregulated compounds have scared physicians into this licensed and certified route. Compounding Pharmacies with the PCAB accreditation is the only way to go for medical offices looking to save money and maintain identical quality controls and measures as the FDA approved manufacturers.

"I've seen eye medications that look like they're 20 years old," John Hancz says, a drug regulator working for the DEA. "The drugs could be old, contaminated, or counterfeit. And if you experience some kind of allergic reaction or other side effect, it's hard to trace the problem and treat it." Tracing a drug that is found to be bad or deadly is a must in the world of pharmaceuticals. If a medical office is obtaining it from Canada and Mexico you will never have the capability to determine which of your patients are at risk following a recall. This alone has physicians on the search for a better and still cheaper alternative to the overpriced branded market.

Whether you're searching for a cheaper price or dodging the doctor's office, the FDA warns against using unapproved drugs. And just because a drug is approved in a foreign country, that doesn't mean it's approved in the United States, in fact, it is illegal. Drug standards and regulations vary from country to country, and the FDA is responsible only for those marketed and sold inside the United States. Again, follow the PCAB accreditation for a safe alternative to foreign pharmaceuticals.

Joe McCallion, a consumer safety officer in the FDA's Office of Regulatory Affairs, sums it up this way: "If you buy drugs that come from outside the U.S., the FDA doesn't know what you're getting, which means safety can't be assured."

Benefits of a Closed System

"Under the FD&C Act, the interstate shipment of any prescription drug that lacks required FDA approval is illegal. Interstate shipment includes importation--bringing drugs from a foreign country into the United States."

Drugs sold in the United States also must have proper labeling that conforms with the FDA's requirements, and must be made in accordance with good manufacturing practices (FDA Approved or PCAB Approved). As part of the FDA's high standards, drugs can be manufactured only at plants registered with the agency, whether those facilities are domestic or foreign. If a foreign firm is listed as a

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manufacturer or supplier of a drug's ingredient on a new drug application, the FDA generally travels to that site to inspect it.

After the FDA approves a drug, manufacturers still are subject to FDA inspections and must continue to comply with good manufacturing practices. "With an unapproved drug, you can't be sure that it has been shipped, handled, and stored under conditions that meet U.S. requirements," McCallion says. "Unless you work with a PCAB accredited pharmacy that takes measures others don't and processes and compounds in an FDA approved facility, it's your only alternative."

Along with legal requirements on manufacturing, U.S. pharmacists and wholesalers must be licensed or authorized in the states where they operate, and limits on how drugs can be distributed lessen the likelihood that counterfeit or poor-quality drugs will turn up. It's because of such safeguards that the process of getting drugs onto U.S. pharmacy shelves is commonly referred to as a "closed" distribution system. Likely, if a physician office is purchasing from Canada, they are not licensed in your state, which means it is *illegal* and putting patients and physicians at a major risk.

Potential Health Risks With Imported Drugs

Quality assurance concerns. Medications that have not been approved for sale in the United States may not have been manufactured under quality assurance procedures designed to produce a safe and effective product.

Counterfeit potential. Some imported medications—even those that bear the name of a U.S.-approved product—may, in fact, be counterfeit versions that are unsafe or even completely ineffective.

Presence of untested substances. Imported medications and their ingredients, although legal in foreign countries, may not have been evaluated for safety and effectiveness in the United States. These products may be addictive or contain other dangerous substances.

Risks of unsupervised use. Some medications, whether imported or not, are unsafe when taken without adequate medical supervision. You may need a medical evaluation to ensure that the medication is appropriate for you and your condition. Or, you may require medical checkups to make sure that you are taking the drug properly, it is working for you, and that you are not having unexpected or life-threatening side effects.

Labeling and language issues. The medication's label, including instructions for use and possible side effects, may be in a language you do not understand or may make medical claims and suggest specific uses that have not been adequately evaluated for safety and effectiveness.

Lack of information. An imported medication may lack information that would permit you to be promptly and correctly treated for a dangerous side effect caused by the drug.

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Demonstrate *Quality* with PCAB Accreditation

While all compounding pharmacies are required to meet the requirements set by their respective state boards of pharmacy, **PCAB Accredited™** denotes a more stringent and comprehensive standard which serve as an assurance that the Accredited Pharmacy has been tested against the profession's most rigorous standards.



PCAB Accreditation requires that a pharmacy:

- ❶ Agree to the PCAB rules and terms of accreditation.
- ❷ Abide by the PCAB Principles of Compounding.
- ❸ Meet or exceed all PCAB quality standards.
- ❹ Pass an extensive on-site inspection.
- ❺ Use only high quality chemicals and equipment.
- ❻ Ensure that compounding pharmacists and technicians receive continuing education and training in compounding.
- ❼ Employ a system of continuous quality improvement.

PCAB Criteria was established by a Standards Committee of compounding pharmacists and nationally recognized experts in the compounding pharmacy profession.

To earn the designation as a **PCAB Accredited™** compounding pharmacy, the pharmacy must complete an extensive application and submission process which documents education, training, licensures, policies, and procedures. The pharmacy must also pass an comprehensive on-site inspection. When the pharmacy is judged to have met the PCAB standards, the pharmacy is awarded the PCAB Seal of Accreditation.

When a pharmacy is PCAB Accredited, it confirms their commitment to providing safe, customized solutions that meet the medical needs of their patients, and the needs of the healthcare providers in their community.



To learn more about PCAB Accreditation, visit:
www.pcab.org or www.pcab.info

US Compounding Pharmacy
2515 College Ave
Conway, AR 72034
Ph: 800-718-3588 Fax: 501-328-3201
www.uscompounding.com



Informed consumers should choose a compounding pharmacy that displays the PCAB Accredited™ Seal.

Filename:

AMAreolutiononcompounds.pdf

APAC00022



American Medical Association RESOLUTION ON COMPOUNDS

via AMA Policy Finder

H-120.945 AMA Action on Non FDA-Approved Compounded Medications

Our AMA:

1. recognizes that compounding pharmacies must comply with current United States Pharmacopeia and National Formulary (USP-NF) compounding monographs, when available, and recommends that they be required to conform with USP-NF General Chapters on pharmaceutical compounding to ensure the uniformity, quality, and safety of compounded medications;
2. recognizes the accreditation program of the Pharmacy Compounding Accreditation Board (PCABTM) and the PCABTM Seal of Accreditation as a means to identify compounding pharmacies that adhere to quality and practice standards, including those set forth in the USP-NF, for the preparation of individualized medications for specific patients;
3. encourages all state boards of pharmacy to require compounding pharmacies in their states to obtain the PCABTM Seal of Accreditation or, alternatively, to satisfy comparable standards that have been promulgated by the state in its laws and regulations governing pharmacy practice; and
4. encourages state boards of pharmacy and the National Association of Boards of Pharmacy (NABP), the umbrella organization for state boards of pharmacy, to work with the United States Food and Drug Administration (FDA) to identify and take appropriate enforcement action against entities that are illegally manufacturing medications under the guise of pharmacy compounding. (BOT Action in response to referred for decision Res. 521, A-06)

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